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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,766

06/27/2003

David Wynn

MCP-5014 NP

7412

27777 7590 07/21/2008
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

07/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/607,766</p>	<p>Applicant(s) WYNN ET AL.</p>	
	<p>Examiner JAMES W. ROGERS</p>	<p>Art Unit 1618</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 June 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because:
The examiner does not find applicants arguments persuasive. As detailed in the previous office action applicants have not provided enough information regarding the dosage form and the time to dry it in order to dry the dosage form to 5% moisture content. While it very well may be obvious to one of ordinary skill in the art to determine the time necessary to dry a pharmaceutical dosage form it is never the less is not described within the specification. A description that does not render a claimed invention obvious does not sufficiently describe that invention. But a description that renders obvious a claimed invention does not necessarily satisfy the written description requirement. *Eli Lilly*, 119 F.3d at 1567, 43 USPQ2d at 1405. Furthermore regarding applicants arguments over the 35 USC 103(a) rejections, Bueller clearly recites the use of tablet formulations as outlined in the previous office action. The examiner stands by his remarks that applicants attempted limitation on the moisture content left after drying at 1050 C is not an actual limitation on the amount of moisture present within the composition that is claimed. Applicants did not actually claim an amount of water present in the composition, rather they only provided for a moisture content of the claimed composition after it was measured by a drying experiment, thus the limitation is a physical property of the composition that is being analyzed by an experimental procedure (assay may be the closest term known to the examiner). Since the compositions are the same they will have the same drying properties. If applicants wish to limit the composition by the amount of moisture (water present) then the examiner suggests amending the claims after RCE to include a limitation for the amount of moisture present within the composition. Of course any new limitation must be supported within applicant's specification. Once again as currently amended applicants claim that the moisture content is no more than 5% after an experimental drying analysis was conducted, however this recitation does not actually limit the moisture content of the composition, rather it limits the drying properties of the composition. Applicants assertions of unexpected results as noted by the examiner in the previous office action is essentially an opinion of the inventor that is conclusionary and subjective in nature (taste and mouth feel) and is not sufficient enough of a showing of unexpected results to remove the previous 35 USC 103(a) rejection.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618